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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/802,013	03/16/2004	Bruce F. Molino	20011/1331	4932												
7590 Michael L. Goldman Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051		11/28/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">CORDERO GARCIA, MARCELA M</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1654</td><td></td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>11/28/2007</td><td>PAPER</td></tr></table>		EXAMINER		CORDERO GARCIA, MARCELA M		ART UNIT	PAPER NUMBER	1654		MAIL DATE	DELIVERY MODE	11/28/2007	PAPER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,013	Applicant(s) MOLINO ET AL.	
	Examiner Marcela M. Cordero Garcia	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-188 is/are pending in the application.
- 4a) Of the above claim(s) 104-188 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the reply and the 1.132 declaration received on July 23, 2007.

Claims 1-188 are pending in the application.

Applicant originally elected with traverse Group I, drawn to cyclosporine compounds, claims 1-103. The species elected by Applicant was a compound of Formula (I) wherein A is an amino acid of Formula (II) and wherein R_0 is CH_3 ; R_1 is $CH=CHC(=O)Me$; X is hydroxyl; B is aminobutyric acid; C is a sarcosine; D is N-methyl leucine; E is valine; F is an N-methyl leucine; G is alanine; H is D-alanine; I is N-methyl leucine; J is N-methyl leucine; and K is N-methyl valine, with claims 1-3 readable thereon. Applicant's elected species was searched and found free of the prior art. Claim 3 is drawn exclusively to this species and would be allowable if written in independent form.

The search was broadened by Examiner, namely, a compound of Formula (I) wherein A is an amino acid of Formula (II) and wherein R_0 is CH_3 ; R_1 is $CR_{13}R_{14}R_{15}$ with $R_{13} = R_{14} = H$ and $R_{15} =$ substituted and unsubstituted C_2-C_6 -straight alkenyl chain; X is hydroxyl; B is a-aminobutyric acid; C is a sarcosine; D is N-methyl-leucine; E is valine; F is an N-methyl leucine; G is alanine; H is D-alanine; I is N-methyl leucine; J is N-methyl leucine; and K is N-methyl valine. The 102(b) and ODP rejections presented in the last Office Action are withdrawn based on Applicant's amendments.

Any rejection from the previous Office Action, which is not restated here, is withdrawn. Claims 104-188 are withdrawn as not drawn to the elected group.

Claims 1-103 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments to claim 1 filed December 22, 2005, i.e., "with the proviso that: (1) when $R_1 = \text{CH}_2\text{CHR}_{23}\text{R}_{24}$, where $R_{23} = \text{H}$ or $R_{24} = \text{H}$, R_{24} or R_{23} , respectively, cannot be substituted $\text{C}_1\text{-C}_6$ -straight alkyl chain, arylalkyl, halogen, hydroxyl, nitrile, or deuterium; (2) when $R_1 = \text{CHO}$, R_o cannot be CH_3 ; and (3) when $R_1 = \text{CH}=\text{CR}_{23}\text{R}_{24}$, R_{23} and R_{24} cannot be H at the same time and, where $R_{23} = \text{H}$ or $R_{24} = \text{H}$, R_{24} or R_{23} , respectively, cannot be substituted and unsubstituted $\text{C}_2\text{-C}_6$ straight alkynyl chain." (see page 7 of claim 1) is deemed new matter because no support was found for such proviso within the instant specification. In addition, the amendment to claim 1, filed on October 20, 2006, amending claim 1, changing the proviso initially entered on December 22, 2005 even further, is also deemed new matter because there appears to be no support within the disclosure for such proviso.

Claims 1-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the

conclusion that the applicant was in possession of the claimed species is sufficient."

MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a cyclic compound of formula I
cyclo (A-B-C-D-E-F-G-H-I-J-K) and A amino acid defined as formula II
N(R_o)CH(CHXCHR₁CH₃)CO No specific activity is claimed for such compounds. The

main claim contains a broad definition of all possible substituents therein, mostly defined also broadly, e.g., $R_1 = \text{CHO}$, $\text{C}(=\text{O})\text{OR}_2$, $\text{C}(\text{O})\text{NR}_3\text{R}_4$, $\text{CH}=\text{N}-\text{Y}$; $\text{CH}(\text{NR}_5\text{R}_6)$; $\text{CH}(\text{OR}_8)\text{R}_9$; $\text{CH}(\text{SR}_{12})_2$; $\text{CR}_{13}\text{R}_{14}\text{R}_{15}$; and *thirty* other broadly defined substituents just for R_1 . The instantly claimed broad formula encompasses a plethora of compounds, which are not adequately described and/or represented in the examples (e.g., specification, pages 44-55 and pages 91-161). A mere description of all the possible/desirable substituents for the instantly claimed compounds does not sufficiently provide ample written since only a very few examples of the instantly claimed compounds are presented which do not represent the full breadth of the instantly claimed broad formula. Please note that, in addition to a very meager number of examples given the broadness of the invention, it appears also that many of the examples are drawn to cyclosporine A (CsA) and not to the newly developed compounds. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with respect all possible compounds encompassed by the claims. The possible structural variations are extremely broad to any a countless number of substituents which are also substituted themselves. Here, though the claims recite some structural characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect the variance in the genus as instantly claimed. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does

"little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Applicants' Arguments

The rejection of claims 1-103 under USC 112 1st paragraph for lack of written descriptive support is respectfully traversed.

It is the US PTO position that the present application lacks written descriptive support for all compounds encompassed by the claims. In addition, the PTO contends that the amendments to claim 1, filed December 22, 2005, and October 20, 2006, introducing provisos lack written description and are new matter. Because no support was found in the specification for such provisos. Applicants respectfully disagree.

The PTO asserts that no support exists in the present application for amended claim 1 containing the provisos. Applicants submit that there is more than ample basis for a claim of such scope. First, the present application is clearly directed to cyclosporine analogue compounds of the type claimed by the amended claim. The scope of the present invention is apparent from the language of the claims, as described above. Specific compounds according to the claimed invention are set forth in Examples 19-23, 25-29, 31-42, 45-63, 65, 67-73, 75, 79-80, 85-97 and 108. This is more than sufficient to demonstrate that applicants had possession of the invention. The

accompanying declaration of Bruce F Molino, PhD under 37 CRF 1.132 demonstrates that a significant number of compounds in accordance with the claimed invention have immunosuppressive activity.

As to the claimed provisos, *In re Johnson*, 558 F.21008, 194 USPQ 1987 (CCPA 1977), the Federal Circuit considered an issue analogous to one here. In that case, a class of thermoplastic polyarylene polyethers was disclosed and claimed in a US patent application filed in 1963 ("the 1963 application"). *Id* at 1011, 194 USPQ at 190. During prosecution, the 1963 application became involved in an interference that resulted in an award of priority adverse to the inventors. *Id* at 1012, 194 USPQ at 191. In 1972, a continuation-in-part application ("the 1972 application") was filed containing claims which differed from the broad claims of the earlier 1963 application by reciting a proviso that excluded, *inter alia*, two species compounds, i.e., the subject matter of the lost interference count. *Id*. At 1013, 194 USPQ at 191. Those claims were rejected by the PTO under 35 USC 102 or 103 on the basis of a Netherlands patent, which was a foreign filed counterpart of the 1963 application. *Id*. at 1013-14, 194 USPQ at 192. While the inventors conceded that the invention was fully disclosed in the Netherlands patent, the contended that the claims are entitled to the benefit of the 1963 filing date under 35 USC 120 and therefore the Netherlands patent was not available as a prior art reference. *Id*. At 1014, 194 USPQ at 192. The PTO found that the claims were not entitled to the 1963 filing date because the newly claimed subject matter in the 1972 application was not described in the 1963 application as required by the first paragraph of the 35 USC 112. *Id*. The PTO Board of Appeals (the "Board") affirmed adding that the

artificial subgenus that was created in the 1972 application was not described in the 1963 application, and would be "new matter" if introduced into either the 1963 application or the 1972 application. *Id.* The Court of Customs and Patent Appeals, however, reversed the Board observing that the applicants were merely excising the invention of another, to which they were not entitled, rather than creating an artificial subgenus or claiming new matter. *Id.* at 1019, 194 USPQ at 196.

Applicants submit that the PTO's written description rejection in the present application is yet another example of the kind of "hypertechnical application" of the written description requirement of 35 USC 112 that was criticized by the Federal Circuit in *In re Johnson*. *Id.* See also *In re Driscoll*, 562 F.2d 1245, 1249, 195 USPQ 434, 438 (CCPA 1977).

The amendments to the claims adding provisos simply delete a number of species from the protection sought so that the applicants can claim less than the full scope of their original disclosure. As noted in *In re Johnson*, claiming less than the full scope of applicants' disclosure is a perfectly legitimate procedure, since "inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. 558 F.2d at 1018, 194 USPQ at 196. *In re Johnson* also noted that "[i]t is for the inventor to decide what bounds of protection he will seek" 558 F.2d at 1018, 194 USPQ at 196 (quoting *In re Saunders* 444 F.2d 599, 607, 170 USPQ 213, 220 (CCPA, 1971)). For the PTO to reject the claims of the present application for lack of written descriptive support would, as stated in *In re Johnson*, "let form triumph

over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed". *Id.*

When the present application contains a broad generic disclosure coupled with extensive examples fully supportive of the limited genus defined by the amended Claims containing the proviso, the PTO cannot assert that applicants have failed to disclose and teach those skilled in the art how to make and use the limited genus, i.e., the disclosed genus minus two of its species, and thus failed to satisfy the written description requirement of 35 USC 112. As the Federal Circuit stated in *In re Johnson*,

The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species there within, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and thus failed to satisfy the requirements of the 112 first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.

558 F. 2d at 1019, 194 USPQ at 196. All that happened here is that applicants narrow their claims to avoid having them read on prior art. As held in *In re Johnson*, the "written description" in the specification supported the claims in the absence of the proviso and "that the specification, having described the whole, necessarily described the part remaining". *Id.* Therefore, the amendments to the claims in the present application are merely excising the invention of another, to which they are not entitled, and are not creating an artificial subgenus, as the PTO contends. *Id.*

Response to Arguments

The declaration under 37 CFR 1.132 filed July 23, 2007 is insufficient to overcome the rejection of claims 1-103 based upon new matter and written description as set forth in the last Office action because: the 3 compounds (27, 50 and 57) that are compared side-by-side with the positive control CsA., and the inhibition by positive control is not expressed in the same units as the reported compounds (e.g., 0.10 ug/mL, 1.0 ug/mL for the compounds vs. IC_{50} for CsA ug/mL). Therefore, the presented data is not commensurate in scope and does not directly compare the inhibition the control.

Applicant's arguments filed 7/23/07 have been fully considered but they are not persuasive for the following reasons:

The subgenus carved in the amendments of 12/22/05 and the amendment of 10/20/06, is herein presented together: "... with the proviso that: (1) when $R_1 = CH_2CHR_{23}R_{24}$, where $R_{23}=H$ or $R_{24}=H$, R_{23} or R_{24} respectively, cannot be substituted C_1 - C_6 straight alkyl chain, arylalkyl, halogen, hydroxyl, nitrile or deuterium or, alternatively when $R_1=CR_{13}R_{14}R_{15}$ wherein $R_{13}=R_{14}=H$, $R_{13}=R_{15}=H$ or $R_{14}=R_{15}=H$, R_{15} , R_{14} or R_{13} , respectively, cannot be substituted C_1 - C_2 -straight alkyl chain; (2) when $R_1=CHO$, R_0 cannot be CH_3 ; (3) when $R_1 = CH=CR_{23}R_{24}$, R_{23} and R_{24} cannot be H at the same time and, where $R_{23}=H$ or $R_{24}=H$, R_{24} or R_{23} , respectively, cannot be substituted and unsubstituted C_2 - C_6 straight alkynyl chain; and (4) when $R_1=CR_{13}R_{14}R_{15}$, wherein $R_{13}=R_{14} = H$, $R_{13}=R_{15}=H$ or $R_{14}=R_{15}$, R_{15} , R_{14} or R_{13} , respectively, cannot be hydrogen, hydroxyl, $COOH$, unsubstituted C_3 -straight alkyl chain, substituted arylalkyl, substituted or unsubstituted C_2 - C_6 straight alkenyl or alkynyl chain, or substituted C_3 -cycloalkyl.

Such amendments lack *ipsis verbis* support, since the newly claimed limitations are not

found within the disclosure. In addition: "While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." See MPEP 2163. The disclosure does not provide any guidance regarding the various provisos entered in the amendments above. Applicants do point out to a series of compounds that are embodied by the carved-out subgenus of the instant amendment. However, one cannot readily conclude, based on the examples alone, that there is support for the amendment introducing a new subgenus as set forth above.

See also MPEP 2163:

The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. See *Wertheim*, 541 F.2d at 263, 191 USPQ at 97 ("[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06. To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). See also *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be "not permanently fixed" to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("[W]here no explicit description of a generic invention is to be found in the specification[,] ... mention of representative

compounds may provide an implicit description upon which to base generic claim language.”); In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads); In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (“To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”) (citations omitted). Furthermore, each claim must include all elements which applicant has described as essential. See, e.g., Johnson Worldwide Associates Inc. v. Zebco Corp., 175 F.3d at 993, 50 USPQ2d at 1613; Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d at 1479, 45 USPQ2d at 1503; Tronzo v. Biomet, 156 F.3d at 1159, 47 USPQ2d at 1833. If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

The provisos above are not disclosed and with the scope of the claim and the support in the specification. Therefore, the new matter rejection and the written description rejections set forth above are still deemed proper and herein maintained.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

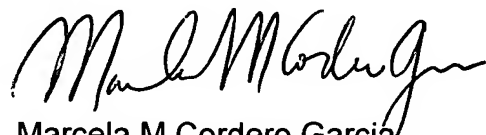
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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